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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,577	12/12/2003	David M. Waisman	101982	2576

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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,577	WAISMAN, DAVID M.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *9-16 and 19-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, claims 2-8, 17 and 18, linking claim 1 and SEQ ID NO: 16 in the reply filed on July 25, 2005 is acknowledged. The traversal is on the ground(s) that groups I-VII have a common element, namely a protein involved in plasminogen activation and any search of group I would necessarily co-extend with the search and examination of groups II-VII. This argument is not found persuasive because although there may be some overlap between the searches of groups I and any of groups II-VII, the existence of a common element does not make the search of multiple inventions co-extensive. Applicant further states that groups I and IV should be rejoined because the assertion of distinctness between groups I and IV does not provide a basis for restriction and no showing has been made that searching and examining groups I and IV together would be an undue burden. This argument is not persuasive because the showing that a product could be used in a materially different process does provide a basis for restriction, see MPEP § 806.05(h). The assertion that no showing exists that search of a product and process together would provide an undue burden is incorrect, such a showing was made in the restriction requirement at paragraph 5. Applicant further traverses the requirement to elect a single sequence and refers to MPEP 803.02 and points out that "the examiner may require a provisional election of species". This quote refers to the situation where two or more of the members of the Markush group are so unrelated and diverse that a prior art reference

anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other members. The situation described in this MPEP section is the rationale behind linking claim practice, which provides that upon allowance of the linking claim of this application (claim 1) the restriction between the sequences will be withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-16 and 19-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 25, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is directed to a composition which modulates the activity of a p11 protein and effects a change in the level of plasminogen activation by a cell. This claim is indefinite because a proper composition claim must have at least two different elements while this claim does not contain any recited elements. Claims 2-8, 17 and 18 are indefinite due to their dependence from claim 1

and because they define, at most, one element of the composition. For the purposes of examination claims 2-8, 17 and 18 have been interpreted as being directed to isolated nucleic acids.

Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 is directed to the composition of "any one of claim 1". The phrase "any one of" indicates a multiply dependent claim but this claim is singularly dependent. Claim 18 is indefinite due to its dependence from claim 17. For the purposes of examination this claim has been interpreted to be dependent from claim 1 alone.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 1 is directed to a composition that modulates activity of a p11 protein and effects a change in the level of plasminogen activation by a cell. This claim defines the composition solely in terms of function without a recitation of structure and thus encompasses all structures that have the recited function, including oligonucleotides, proteins, antibodies, small organic molecules and inorganic molecules. Claim 1 also encompasses any composition that modulates activity of any p11 protein from any species. Claims 2-4 limit claim 1 by stating the composition is a polynucleotide that may be an antisense p11 polynucleotide. Claims 17 and 18 limit claim 1 by stating the cell is a cancer cell that may be one of several recited types of cancer.

The specification describes compositions that modulate activity of p11 as including antisense and sense p11 polynucleotides, siRNAs specific to p11, inhibitory antibodies, p11-receptor blocking peptides, p11 antagonists and agonists and soluble fragments of the p11 protein receptor. As noted above, the claims also encompass small organic molecules and inorganic molecules. The specification discloses several antisense polynucleotides and siRNAs and one sense polynucleotide, presumably directed to human p11.

The specification does not describe the structure of nucleic acid modulators to a p11 protein from a species other than the p11 targeted in the working examples (presumably human) that correspond to the function of modulating p11 and plasminogen activation in a cell. The specification further fails to describe the structure of any non-nucleic acid modulators of a p11 protein that would correspond to the function of modulating the activity of a p11 and plasminogen activation by a cell.

In order for the written description provision of 35 USC 112, first paragraph to be satisfied, applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed. For example, MPEP 2163 states in part,

> "An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.")."

The skilled artisan cannot envision the detailed structure of the encompassed compositions that modulate p11 and plasminogen activation, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

Therefore, while the specification provides adequate description of the antisense, sense and siRNA nucleic acid modulators targeted to the p11 described in the working examples, the full breadth of the many types of possible modulators of p11 from any species encompassed by the claims do not meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 17 and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yao et al. (Journal of Biological Chemistry 1999, vol. 274, pages 17202-17208).

Claims 1-4 are directed to compositions including antisense p11 polynucleotides that inhibit p11 production and change the level of plasminogen activation in a cell. Claim 17 is directed to compositions that change the level of plasminogen activation in cancer cells while claim 18 recites specific types of cancer cells.

Yao et al. disclose a plasmid that produces an antisense p11 polynucleotide and disclose that this plasmid decreases p11 expression in HeLa cells, a type of cancer cell. Although Yao et al. do not disclose that this plasmid changes the level of plasminogen activation in the cell, the prior art oligonucleotide is an antisense p11 polynucleotide.

Furthermore, since the prior art oligonucleotides meet all the structural limitations of the claims, the prior art oligonucleotides would then be considered to change the "level of plasminogen activation" as claimed, absent evidence to the contrary. See, for example, MPEP 2112, which states

> "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 USC 102 and 103, expressed as

a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 USC 103 and for anticipation under 35 USC 102' *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 USC 102/103 rejection is appropriate for these types of claims as well as for composition claims."

Thus, Yao et al. disclose all limitations of and anticipate claims 1-4, 17 and 18.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The central FAX Number is 571-273-8300.

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provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
September 22, 2005

J.D. SCHULTZ, Ph.D.
PATENT EXAMINER